

Sub B1
AT
detecting expression of cyclin E in the nuclei and/or the cytoplasm of endometrial gland cells in an endometrial tissue sample from on or after day 20 of an idealized 28 day menstrual cycle from a woman suspected of being infertile;

wherein

expression of cyclin E in the nuclei of greater than 5% of the gland cells indicates endometrial glandular developmental arrest, and/or

expression of cyclin E of greater than 1+ staining intensity in the cytoplasm of greater than 10% of the gland cells indicates endometrial glandular developmental arrest.

Sub B2
64 (New). A method of claim 1 wherein said woman is suspected of being infertile.

65 (New). The method of claim 64 wherein the expression of cyclin E is detected by an immunohistochemistry assay.

66 (New). The method of claim 64 wherein the cycle day is determined by examining the stroma cells in the sample.

A2
67 (New). The method of claim 64 wherein expression of cyclin E is detected in the nuclei of greater than 10% of the gland cells in the sample is indicative of endometrial glandular developmental arrest.

68 (New). The method of claim 64 wherein the cycle day is day 24 of an idealized 28 day menstrual cycle.

69 (New). The method of claim 64 further comprising the step of detecting the expression of p27

in the nuclei of gland cells in a serial section of the sample.

70 (New). The method of claim 64 further comprising the step of detecting the expression of progesterone receptor in the gland cells in a serial section of the sample.

71 (New). The method of claim 64 further comprising the step of detecting the expression mouse ascites golgi mucin MAG in the gland cells in a serial section of the sample.

A2
72 (New). The method of claim 64 further comprising the steps of detecting the expression of p27 in the nuclei of gland cells in a serial section of the sample and either detecting the expression of progesterone receptor in the gland cells in a serial section of the sample or detecting the expression of MAG in the gland cells in a serial section of the sample or both.

73 (New). The method of claim 64 further comprising the step of detecting expression of cyclin E in the nuclei and/or the cytoplasm of endometrial gland cells in an endometrial tissue sample from on or before day 18 of an idealized 28 day menstrual cycle from the woman.

74 (New). The method of claim 64 further comprising the step of detecting expression of cyclin E in the nuclei and/or the cytoplasm of endometrial gland cells in an endometrial tissue sample from day 15 an idealized 28 day menstrual cycle from the woman.

75 (New). The method of claim 64 further comprising the step of detecting expression of p27 in the nuclei of endometrial gland cells in an endometrial tissue sample from on or before day 18 of an idealized 28 day menstrual cycle from the woman.

76 (New). The method of claim 64 further comprising the step of detecting expression of p27 in the nuclei of endometrial gland cells in an endometrial tissue sample from before day 17 of an idealized 28 day menstrual cycle from the woman wherein expression of p27 is indicative of accelerated endometrial glandular development.

77 (New). The method of claim 64 further comprising the step of detecting expression of progesterone receptor in the gland cells in an endometrial tissue sample from before day 18 of an idealized 28 day menstrual cycle from the woman.

A2
78 (New). The method of claim 64 further comprising the step of detecting the expression of MAG in the gland cells in an endometrial tissue sample from on or before day 18 of an idealized 28 day menstrual cycle from the woman.

79 (New). The method of claim 64 further comprising at least two of the following steps of:

- a) detecting the expression of cyclin E in the nuclei and/or cytoplasm of the gland cells in an endometrial tissue sample from on or before day 18 of a an idealized 28 day menstrual cycle from the woman;
- b) detecting the expression of p27 in the nuclei of gland cells in an endometrial tissue sample from on or before day 18 of an idealized 28 day menstrual cycle from the woman;
- c) detecting expression of progesterone receptor in gland cells in an endometrial tissue sample on or before day 18 of an idealized 28 day menstrual cycle from the woman;
- d) detecting the expression of MAG in the gland cells in an endometrial tissue sample from on or before day 18 of an idealized 28 day menstrual cycle from the woman;

wherein said two or more steps are performed on serial sections of the sample.

DOCKET NO.: KLI-0002
PATENT APPLICATION

SERIAL NO.: 09/801,470
FILED: MARCH 8, 2001

Sub B4 }
80 (New). A method of claim 64 wherein said woman is undergoing a hormonal protocol to produce a mock trial.

A2
81 (New). A method of claim 1 wherein said woman is undergoing a hormonal protocol to produce a mock trial.

82 (New). A method of claim 17 wherein said woman is undergoing a hormonal protocol to produce a mock trial.

REMARKS

Claims 1-63 are in the application.

Claims 1-63 have been subject to a requirement for restriction.

By way of this amendment, Applicants have canceled claims 25-36 and 54-63 without prejudice, amended claim 1 and added new claims 64-82.

Upon entry of the amendment, claims 1-24, 37-53 and 64-82 will be pending.

Restriction Requirement

Applicants elect Group I, claim 1-24 for examination. Applicants respectfully request reconsideration of the restriction requirement with respect to claims 37-53. Applicants respectfully urge that claims 37-53 are directed at methods of identifying abnormal endometrial development in patients undergoing a hormone protocol mock cycle and not hormone replacement therapy as claims in claims 54-60. Applicants respectfully urge the methods of evaluating the hormone protocol mock cycle as claimed in claims 37-53 more closely related to the subject matter in elected Group I and respectfully request that the Examiner reconsider the restriction requirement with respect to claims 37-53 and combine those claims with Group I for examination.